Site initiation visit (SIV) training to improve practitioners' confidence in recruiting to a challenging critical care trial

Poster · May 2017

DOI: 10.13140/RG.2.2.27132.54408

11 authors, including:

Louise Roper
University of Liverpool
28 PUBLICATIONS **75** CITATIONS
SEE PROFILE

Mark D Lyttle
University Hospitals Bristol NHS Foundation …
64 PUBLICATIONS **181** CITATIONS
SEE PROFILE

Anand Iyer
Alder Hey Children's NHS Foundation Trust &…
27 PUBLICATIONS **116** CITATIONS
SEE PROFILE

Richard Appleton
Alder Hey Children's NHS Foundation Trust
58 PUBLICATIONS **1,992** CITATIONS
SEE PROFILE

EcLiPSE

Site initiation visit (SIV) training to improve practitioners' confidence in recruiting to a challenging critical care trial

Kerry Woolfall, Louise Roper, Amy Humphreys, Mark Lyttle, Shrouk Messahel, Elizabeth Lee, Joanne Noblet, Anand Iyer, Carrol Gamble, Helen Hickey and Richard Appleton

Contact
k.woolfall@liverpool.ac.uk
Consent@liverpool.ac.uk
@eclipsestudy

Aim

To evaluate **the effectiveness of site initiation visit (SIV) training on healthcare practitioners' (HCP) confidence in the recruitment of patients to EcLiPSE**. The interactive SIV training included:

- protocol presentations from the trial team;
- screening and randomisation simulation (video and real-time);
- a video of the consent recruitment conversation informed by feasibility work with parents (CONNECT study), and
- a question and answer session.

EcLiPSE is an un-blinded pragmatic, randomised and controlled trial that compares the use of **levetiracetam *versus* phenytoin** in the treatment of status epilepticus in children.

Challenges to the success of EcLiPSE include: a vulnerable target population (children aged 6 months to <18 years); the need to administer the intervention without prior informed consent (termed, 'deferred consent'); and the use of levetiracetam, a relatively new anti-epileptic medication which is not traditionally usually used in this acute clinical setting.

Design

Mixed method study including a 14 item questionnaire administered before and after the site training and telephone interviews with EcLiPSE recruiters in the first 12 months after site opening.

Setting: UK hospitals.

Participants: 26/30 (87%) EcLiPSE sites including 170/333 (51%) practitioners, of which 125/333 (38%) were included in analysis. We interviewed Principal Investigators (n=5) or lead research nurses (n=3) between 6-12 (mean= 8.1) months after training.

Site initiation visit training at Bristol Royal Hospital for Children

Simulation practice during site initiation training in The Children's Hospital, Cardiff

Recruitment conversation training video for staff taking consent, filmed at The University of Liverpool

Findings

- For most sites EcLiPSE was their first Emergency Department led paediatric clinical trial.
- Before training, over half (69/115, 60.2%) of practitioners anticipated that there would be practical or logistical difficulties issues in participating in EcLiPSE.
- Practitioners spoke of the importance of getting all staff "on board" and enthused.
- Following training there was a **significant positive change in practitioners' confidence** in explaining: the study (p=<0.001); randomisation (p=<0.001), research without prior consent (p=<0.001), and responding to parents who object to the study (p=<0.001).
- **Valued aspects:** videos, parent perspectives, and the number of EcLiPSE team members involved in training and attending the SIV.

"Good to see how nurse handled difficult questions"
(P27, Research nurse)

"I think enough of you (EcLiPSE team) turned up"
(P4, Principal investigator)

Conclusions

Interactive site training can effectively assist important practitioners 'buy in' for challenging clinical trials. Our findings highlight how **pre-trial feasibility work with parents can improve practitioners confidence in recruitment and consent seeking** in a paediatric critical care trial.

The EcLiPSE study was funded by the National Institute for Health Research HTA programme (project number 12/127/134)